K094005

510 (k) Summary

MAY - 5 2010

1. Submitter Information

Company name TaiDoc Technology Corporation
Contact person Nicky Pan
Address 6F, No. 127, Wugong 2nd Rd,
Wugu Township, Taipei County,
24888, Taiwan
Phone (886-2) 6625-8188
FAX (886-2) 6625-0288
E-mail nicky@taidoc.com
Date Prepared Dec 23rd, 2009

2. Name of Device

Trade Names: FORA G31a/ TD-4256A Blood glucose monitoring system and FORA G31b/ TD-4256B Blood Glucose Monitoring System
Common Names/Descriptions Blood Glucose Meter
Blood Glucose Test Strips
Classification Names Class II devices
(21 CFR Section 862.1345, Glucose Test System)

3. Predicate Device

Trade/Proprietary Name: FORA G30 Blood Glucose Monitoring System (Model TD-4241)
Common/Usual Name: Blood Glucose Meter
Blood Glucose Test Strips
Manufacturer TaiDoc Technology Corporation
510 (k) Number K090187

4. Device Description

FORA G31a/ TD-4256A Blood glucose monitoring system and FORA G31b/ TD-4256B Blood Glucose Monitoring System consist of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

5. Intended Use

FORA G31a/TD-4256A Blood glucose monitoring system:

FORA G31a/TD-4256A is intended for in vitro use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative testing sites in the FORA G31a/TD-4256A Blood Glucose Monitoring system can be used only during steady-state blood glucose conditions.

FORA G31 and TD-4256 Blood Glucose Test Strips are used with the FORA G31a/TD-4256A glucose meter in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the alternative sites specified above.

FORA Control Solutions/Taidoc Control Solutions are intended for use with the FORA G31a/TD-4256A Blood Glucose meter to check that both the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

FORA G31b/TD-4256B Blood glucose monitoring system:

FORA G31b/TD-4256B is intended for in vitro use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative testing sites in the FORA G31a/TD-4256A Blood Glucose Monitoring system can be used only during steady-state blood glucose conditions.

FORA G31 and TD-4256 Blood Glucose Test Strips are used with the FORA G31b/TD-4256B glucose meter in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the alternative sites specified above.

FORA Control Solutions/Taidoc Control Solutions are intended for use with the FORA G31b/TD-4256B Blood Glucose meter to check that both the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

6. Comparison to Predicate Device

FORA G31a/ TD-4256A Blood glucose monitoring system and FORA G31b/ TD-4256B Blood Glucose Monitoring System have equivalent technological characteristics as the FORA G30 Blood Glucose Monitoring System (K090187, Model TD-4241). FORA G31a/ TD-4256A Blood glucose monitoring system and FORA G31b/ TD-4256B Blood Glucose Monitoring System also have the same intended use as the FORA G30 Blood Glucose Monitoring System (Model TD-4241).

7. Performance Studies

The performance of FORA G31a/ TD-4256A Blood glucose monitoring system and FORA G31b/ TD-4256B Blood Glucose Monitoring System was studied in the laboratory. The studies demonstrated that the performance of this system meets its intended use.

8. Conclusion

FORA G31a/ TD-4256A Blood glucose monitoring system and FORA G31b/ TD-4256B Blood Glucose Monitoring System demonstrate satisfactory performance and are suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Taidoc Technology Corporation
c/o Mr. Nicky Pan
Specialist of Regulatory Affairs
6F, No. 127, Wugong 2nd Road,
WUGU Township
Taipei County, China (Taiwan) 248

JUL - 8 2010

Re: k094005
Trade Name: FORA G31a/TD-4256A Blood glucose monitoring system
FORA G31b/TD-4256B Blood glucose monitoring system
Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: February 04, 2010
Received: March 01, 2010

Dear Mr. Pan:

This letter corrects our substantially equivalent letter of May 5, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number:K094005

Device Name: FORA G31a/TD-4256A Blood glucose monitoring system

Indications for Use:

FORA G31a/TD-4256A is intended for in vitro use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative testing sites in the FORA G31a/TD-4256A Blood Glucose Monitoring system can be used only during steady-state blood glucose conditions.

FORA G31 and TD-4256 Blood Glucose Test Strips are used with the FORA G31a/TD-4256A glucose meter in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the alternative sites specified above.

FORA Control Solutions/Taidoc Control Solutions are intended for use with the FORA G31a/TD-4256A Blood Glucose meter to check that both the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

Prescription Use _____ AND/OR Over-The-Counter Use __X_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K094005

Indications for Use

510(k) Number:K094005

Device Name: FORA G31b/TD-4256B Blood glucose monitoring system

Indications for Use:

FORA G31b/TD-4256B is intended for in vitro use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates. The alternative testing sites in the FORA G31b/TD-4256B Blood Glucose Monitoring system can be used only during steady-state blood glucose conditions.

FORA G31 and TD-4256 Blood Glucose Test Strips are used with the FORA G31b/TD-4256B glucose meter in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the alternative sites specified above.

FORA Control Solutions/Taidoc Control Solutions are intended for use with the FORA G31b/TD-4256B Blood Glucose meter to check that both the glucose meter and test strips are working properly. These solutions contain a known range of glucose, as indicated on the bottles.

Prescription Use _____ AND/OR Over-The-Counter Use __X_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Division Sign-Off

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